

# United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

DATE MAILED: 08/08/2005

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/827,114	04/19/2004	Jeffrey I. Frank	ARCD:394US	1458
75	08/08/2005		EXAM	INER
Michael C. Barrett, Esq. FULBRIGHT & JAWORSKI, L.L.P.			WILLIAMS, KENNETH C	
Suite 2400	c JA W OKSKI, E.E.I .		ART UNIT	PAPER NUMBER
600 Congress Avenue			3739	
Austin, TX 78	3701		DATE MAILED: 00/00/200	•

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
	10/827,114	FRANK ET AL.					
Office Action Summary	Examiner	Art Unit					
	Kenneth C. Williams	3739					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1) Responsive to communication(s) filed on 19 A 2a) This action is FINAL 2b) This 3) Since this application is in condition for alloware closed in accordance with the practice under E	action is non-final.  nce except for formal matters, pro	•	merits is				
·							
A) Claim(s) 1-32 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) 1-32 is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) are subject to restriction and/or election requirement.							
Application Papers							
9) ☐ The specification is objected to by the Examiner.  10) ☐ The drawing(s) filed on 19 April 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119	•						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 02/02/2005.	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:	ate	-152)				

Application/Control Number: 10/827,114 Page 2

Art Unit: 3739

#### DETAILED ACTION

#### Election/Restrictions

1. During a telephone conversation with Michael C. Barrett on June 27, 2005 a provisional election was requested by the current examiner. Upon further review, the examiner withdraws the election restriction and claims 1-32 will be examined.

#### Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

# **Drawings**

1. The drawings are objected to because Figures 8 and 9 are illegible. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency.

Application/Control Number: 10/827,114 Page 3

Art Unit: 3739

Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

# Specification

- 4. The disclosure is objected to because of the following informalities:
  - a. A comma is missing on page 5, line 25.
  - b. The incorrect element is cited on page 12, line 11, "inner tube 14".
  - c. The word "control" on page 14, line 30, should be omitted or incorporated into a sentence.
  - d. The word "limited" on page 15, line 3, should be omitted or incorporated into a sentence.
  - e. The unit of measure is incorrect on page 26, lines 14 and 17.
  - f. The word "lessor" on page 27, line 15, should be -lesser-.
  - g. The word "brain" on page 28, line 1, should be -brains-.
  - h. The word "stoke" on page 28, line 4, should be -stroke-.

Appropriate correction is required.

## Claim Objections

5. Claim 5, 23, 26 and 30 are objected to because of the following informality:

Art Unit: 3739

a. Claim 5 discloses "The probe of claim 5, further comprising an isolation member coupling the second temperature sensor to the outer tube". "The probe of claim 5" lacks proper antecedent basis in claim 5.

Page 4

- b. Claim 23 discloses "determining a health of the tissue". The examiner suggests, "determining a health of the tissue" should read –determining the health of the tissue–.
- c. Claim 26 discloses "inserting a probe into the tissue, the probe having concentric passageways and a temperature sensor; inserting a second temperature sensor into the tissue at a predetermined distance from the probe".

  The examiner suggests "a temperature sensor" should read —a first temperature sensor—.
- d. Claim 30 discloses "indicating a health of the tissue". The examiner suggests, "indicating a health of the tissue" should read –indicating the health of the tissue–.

Appropriate correction is required.

#### Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it

Application/Control Number: 10/827,114 Page 5

Art Unit: 3739

pertains, or with which it is most nearly connected, to make and/or use the invention.

There is no mention of a drainage conduit in the specification.

# Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 29-32 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The computer readable media described in the specification as "Such software may be stored on any computer readable media such as but not limited to floppy disk, hard disk, compact disk, DVD, tape, flash memory, firmware on an ASIC, or any other storage means" (page 17, lines 17-20) is non-statutory because this reads on tangible and intangible storage means.

# Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States
- 10. Claims 1-4,7,8 and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Milder (U.S. Patent No. 5281215).
  - a. In regards to claim 1, Milder discloses a heat transfer probe comprising "an inner tube having an opening", (See Figure 1, element 14, also see column 3, line 33), "an outer tube surrounding the inner tube and configured to receive

Art Unit: 3739

working fluid from the inner tube through the opening", (See Figure 1, element 16, also see column 3, line 31), "a tip adjacent the opening and which terminates the inner and outer tubes", (See Figure 1, element 12, also see column 3, line 28), "a first temperature sensor coupled to the tip", (See Figure 14, element 122, also see column 7, lines 32-38).

Page 6

- b. In regards to claim 2, Milder discloses a heat transfer probe comprising "the first temperature sensor being connected to the tip", (See Figure 14, element 122, also see column 7, lines 32-38).
- c. In regards to claim 3, Milder discloses a heat transfer probe comprising "the inner and outer tubes defining concentric channels", (See column 8, lines 32-33).
- d. In regards to claim 4, Milder discloses a heat transfer probe comprising "a second temperature sensor spaced apart from the first temperature sensor", (See Figure 14, element 122, also see column 7, lines 36-40).
- e. In regards to claim 6, Milder discloses a heat transfer probe comprising "a third temperature sensor coupled to an outlet of the outer tube", (See Milder Figure 14, element 122 below, arrows mark the location of the first, second and third temperature sensors).
- f. In regards to claim 7, Milder discloses a heat transfer probe comprising "the inner tube comprising a first material", (See Figure 1, element 14), "the outer tube comprising a second material", (See Figure 1, element 16), "the tip

Art Unit: 3739

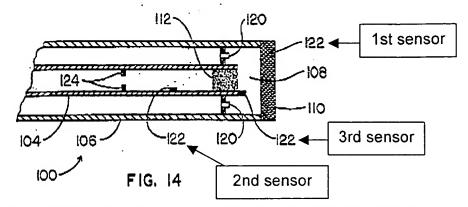
comprising a third material having a thermal conductivity different from that of the first or second material", (See Figure 1, element 22, column 3, lines 39-45).

Page 7

- g. In regards to claim 8, Milder discloses a heat transfer probe comprising "the first and second material being the same", (See column 5, lines 39-49).
- h. In regards to claim 10, Milder discloses a heat transfer probe comprising "the temperature sensor comprising a thermocouple", (See Figure 14, element 122, also see column 7, lines 29-31).
- i. In regards to claim 11, Milder discloses a heat transfer probe comprising "an inner channel configured to transport working fluid from an inner inlet to an inner outlet", (See Figure 1, element 14, see also column 3, lines 42-45), "a tip configured to receive at least a portion of the working fluid from the inner outlet, (See Figure 1, element 12, see also column 3, lines 42-45), "a concentric outer channel configured to transport the working fluid from the inner outlet to an outer outlet", (See Figure 1, element 16, see also column 4, lines 26-32), "a first temperature sensor coupled to the tip", (See Figure 14, element 122, see also column 7, lines 32-38), "a second temperature sensor spaced apart from the first temperature sensor", (See Figure 14, element 122, see also column 7, lines 38-40).

Application/Control Number: 10/827,114 Page 8

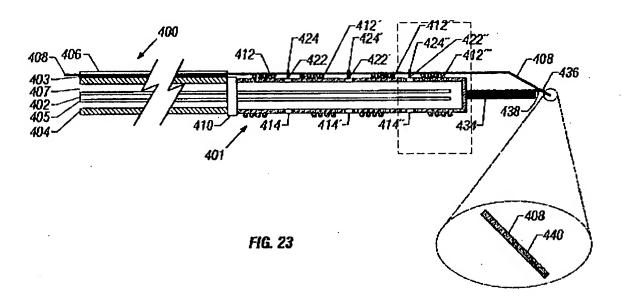
Art Unit: 3739



- 11. Claims 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Dobak, III et al. (U.S. Patent No. 6312452).
  - a. In regards to claim 15, Dobak, III et al. discloses a heat transfer probe comprising "an inner tube having an opening", (See Figure 3, element 42), "an outer tube surrounding the inner tube and configured to receive working fluid from the inner tube through the opening", (See Figure 3, element 46, see also column 11, lines 10-13), "a tip adjacent the opening that terminates the inner and outer tubes", (See Dobak, III et al. Figure 23 below, the area contained in the rectangular box is designated as the tip by the examiner), "a temperature sensor coupled to the tip", (See Figure 23, element 440, see also column 22, lines 29-31), "a source for delivering working fluid to the inner tube and to receive working fluid from the outer tube", (See Figure 25, element 452, see also column 22, lines 62-64), "a pump coupled to the source", (See column 15, lines 6-10), "a controller to control the flow of working fluid to effect heating or cooling of tissue adjacent the probe", (See Figure 25, element 458, see also column 22, lines 59-62).
  - b. In regards to claim 16, Dobak, III et al. discloses a heat transfer probe comprising "the controller receiving feedback from the temperature sensor to

Art Unit: 3739

adaptively control the flow of working fluid based on a sensed temperature", (See column 22, lines 59-62).



Claim Rejections - 35 USC § 103

- 12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 13. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 3739

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Milder (U.S. Patent No. 5281215), further in view of Dobak, III et al. (U.S. Patent No. 6312452).

In regards to claim 5, Milder discloses a heat transfer probe comprising "an inner tube having an opening; an outer tube surrounding the inner tube and configured to receive working fluid from the inner tube through the opening; a tip adjacent the opening and which terminates the inner and outer tubes; a first temperature sensor coupled to the tip; and a second temperature sensor spaced apart from the first temperature sensor".

Milder does not disclose "an isolation member coupling the second temperature sensor to the outer tube". Attention is directed to the Dobak, III et al. reference, which in a similar field of endeavor discloses a heat transfer probe with a thermocouple mounted on the end of a guidewire, which is coupled to the outer tube of the probe. It would have been obvious to one having ordinary skill in the art using the teaching of Dobak, III et al. to utilize an isolation member to couple a temperature sensor to the outer tube in order to monitor the temperature of a tissue at a distance away from the probe.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Milder(U.S. Patent No. 5281215), further in view of Bliweis (U.S. Patent No. 6179831).

In regards to claim 9, Milder discloses a heat transfer probe comprising "an inner tube having an opening; an outer tube surrounding the inner tube and configured to receive working fluid from the inner tube through the opening; a tip adjacent the opening

Art Unit: 3739

and which terminates the inner and outer tubes; and a first temperature sensor coupled to the tip".

Milder does not disclose "a probe holder coupled to the outer tube". Attention is directed to the Bliweis reference, which in a similar field of endeavor discloses a heat transfer probe with a probe holder coupled to the outer tube of the probe (Figure 5, element 32; column 6,lines 62-64). It would have been obvious to one having ordinary skill in the art using the teaching of Bliweis to utilize a probe holder to safely operate the probe.

- 16. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milder (U.S. Patent No. 5281215), further in view of Dobak, III et al. (U.S. Patent No. 6312452).
  - a. In regards to claim 12, Milder discloses a heat transfer probe comprising "an inner tube having an opening and comprising a first material; an outer tube surrounding the inner tube, comprising a second material, and configured for fluid communication with the inner tube through the opening, the inner and outer tubes defining concentric channels; a tip adjacent the opening, comprising a third material having a thermal conductivity different from that of the first or second material, and terminating the inner and outer tubes; a first temperature sensor coupled to the tip and a second temperature sensor spaced apart from the tip and the first temperature sensor".

Milder does not disclose "an isolation member coupling the second temperature sensor to the outer tube". Attention is directed to the Dobak, III et al.

reference, which in a similar field of endeavor discloses a heat transfer probe with a thermocouple mounted on the end of a guidewire, which is coupled to the outer tube of the probe. It would have been obvious to one having ordinary skill in the art using the teaching of Dobak, III et al. to utilize an isolation member to couple a temperature sensor to the outer tube in order to monitor the temperature of a tissue at a distance away from the probe.

b. In regards to claim 13, Milder discloses a heat transfer probe comprising "an inner tube having an opening and comprising a first material; an outer tube surrounding the inner tube, comprising a second material, and configured for fluid communication with the inner tube through the opening, the inner and outer tubes defining concentric channels; a tip adjacent the opening, comprising a third material having a thermal conductivity different from that of the first or second material, and terminating the inner and outer tubes; a first temperature sensor coupled to the tip and a second temperature sensor spaced apart from the tip and the first temperature sensor; a third temperature sensor coupled to an outlet of the outer tube".

Milder does not disclose "an isolation member coupling the second temperature sensor to the outer tube". Attention is directed to the Dobak, III et al. reference, which in a similar field of endeavor discloses a heat transfer probe with a thermocouple mounted on the end of a guidewire, which is coupled to the outer tube of the probe. It would have been obvious to one having ordinary skill in the art using the teaching of Dobak, III et al. to utilize an isolation member to

Art Unit: 3739.

couple a temperature sensor to the outer tube in order to monitor the temperature of a tissue at a distance away from the probe.

c. In regards to claim 14, Milder discloses a heat transfer probe comprising "an inner tube having an opening and comprising a first material; an outer tube surrounding the inner tube, comprising a second material, and configured for fluid communication with the inner tube through the opening, the inner and outer tubes defining concentric channels; a tip adjacent the opening, comprising a third material having a thermal conductivity different from that of the first or second material, and terminating the inner and outer tubes; a first temperature sensor coupled to the tip and a second temperature sensor spaced apart from the tip and the first temperature sensor; the first and second materials being the same".

Milder does not disclose "an isolation member coupling the second temperature sensor to the outer tube". Attention is directed to the Dobak, III et al. reference, which in a similar field of endeavor discloses a heat transfer probe with a thermocouple mounted on the end of a guidewire, which is coupled to the outer tube of the probe. It would have been obvious to one having ordinary skill in the art using the teaching of Dobak, III et al. to utilize an isolation member to couple a temperature sensor to the outer tube in order to monitor the temperature of a tissue at a distance away from the probe.

17. Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milder (U.S. Patent No. 5281215), further in view of Hammack et al. (U.S. Patent No. 6679906).

Art Unit: 3739

Page 14

a. In regards to claim 17, Milder discloses "a probe adapted to be inserted into tissue, the probe comprising first and second concentric channels, the first and second concentric channels each having an inlet and an outlet; a source of working fluid in fluid communication with the first and second concentric channels; a pump operatively associated with the source and probe; a first temperature sensor mounted to the probe and adapted to monitor the temperature of the tissue engaging the probe".

Milder does not disclose "a second temperature sensor mounted radially from the probe and adapted to monitor the temperature of the tissue engaging second temperature sensor". Attention is directed to the Hammack et al. reference, which in a similar field of endeavor discloses a temperature sensor mounted radially from the probe and adapted to monitor the temperature of the tissue. It would have been obvious to one having ordinary skill in the art using the teaching of Hammack et al. to place a temperature sensor radially from the probe in order to monitor the temperature of a tissue at a distance radially away from the probe.

b. In regards to claim 18, Milder discloses "a probe adapted to be inserted into tissue, the probe comprising first and second concentric channels, the first and second concentric channels each having an inlet and an outlet; a source of working fluid in fluid communication with the first and second concentric channels; a pump operatively associated with the source and probe; a first temperature sensor mounted to the probe and adapted to monitor the

Art Unit: 3739

temperature of the tissue engaging the probe". It is noted by the examiner that there is no support for a "drainage conduit" in the specification. Therefore, Milder discloses an outer lumen, element 16 that returns the cooling fluid to the fluid reservoir (Figure 1, element 16; column 4, lines 26-32). The examiner interprets element 16 as a "drainage conduit".

Page 15

Milder does not disclose "a second temperature sensor mounted radially from the probe and adapted to monitor the temperature of the tissue engaging second temperature sensor". Attention is directed to the Hammack et al. reference, which in a similar field of endeavor discloses a temperature sensor mounted radially from the probe and adapted to monitor the temperature of the tissue. It would have been obvious to one having ordinary skill in the art using the teaching of Hammack et al. to place a temperature sensor radially from the probe in order to monitor the temperature of a tissue at a distance radially away from the probe.

c. In regards to claim 19, Milder discloses "a probe adapted to be inserted into tissue, the probe comprising first and second concentric channels, the first and second concentric channels each having an inlet and an outlet; a source of working fluid in fluid communication with the first and second concentric channels; a pump operatively associated with the source and probe; a first temperature sensor mounted to the probe and adapted to monitor the temperature of the tissue engaging the probe and a controller to control the flow of working fluid to effect a temperature change of the material".

Art Unit: 3739

Milder does not disclose "a second temperature sensor mounted radially from the probe and adapted to monitor the temperature of the tissue engaging second temperature sensor". Attention is directed to the Hammack et al. reference, which in a similar field of endeavor discloses a temperature sensor mounted radially from the probe and adapted to monitor the temperature of the tissue. It would have been obvious to one having ordinary skill in the art using the teaching of Hammack et al. to place a temperature sensor radially from the probe in order to monitor the temperature of a tissue at a distance radially away from the probe.

Page 16

d. In regards to claim 20, Milder discloses "a probe adapted to be inserted into tissue, the probe comprising first and second concentric channels, the first and second concentric channels each having an inlet and an outlet; a source of working fluid in fluid communication with the first and second concentric channels; a pump operatively associated with the source and probe; a first temperature sensor mounted to the probe and adapted to monitor the temperature of the tissue engaging the probe and a controller to control the flow of working fluid to effect a temperature change of the material".

Milder does not disclose "a second temperature sensor mounted radially from the probe and adapted to monitor the temperature of the tissue engaging second temperature sensor and the controller receiving feedback from the first or second temperature sensor to adaptively control the flow of working fluid based on a sensed temperature". Attention is directed to the Hammack et al. reference,

Art Unit: 3739

which in a similar field of endeavor discloses a temperature sensor mounted radially from the probe and adapted to monitor the temperature of the tissue. The Hammack et al. reference also discloses a feedback controller to monitor the temperature of the first or second temperature sensor to adaptively control the flow of working fluid based on a sensed temperature. It would have been obvious to one having ordinary skill in the art using the teaching of Hammack et al. to place a temperature sensor radially from the probe in order to monitor the temperature of a tissue at a distance radially away from the probe. Also, it would have been obvious to one having ordinary skill in the art using the teaching of Hammack et al. to use a feedback controller to monitor the temperature of a first or second temperature sensor to adaptively control the flow of working fluid because the tissue proximate the target tissue should not be unduly influenced by the temperature of the heat transfer probe.

Page 17

- 18. Claims 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milder (U.S. Patent No. 5281215), further in view of Lalonde et al. (U.S. Patent No. 6270493).
  - a. In regards to claim 21, Milder discloses a method comprising "transporting working fluid form a source through an inner channel of a probe to change a temperature of tissue adjacent the probe; transporting the working fluid through a concentric outer channel of the probe back to the source; sensing a first temperature of the tissue at a first location using a first temperature sensor coupled to the probe".

Art Unit: 3739

Milder does not disclose "sensing a second temperature of the tissue at a second location using a second temperature sensor spaced apart from the first temperature sensor." Attention is directed to the Lalonde et al. reference, which in a similar field of endeavor discloses sensing temperature of tissue at multiple locations. It would have been obvious to one having ordinary skill in the art using the teaching of Lalonde et al. to sense the temperature of tissue at a second location because it is beneficial to monitor the temperature of a tissue at a second location in order to prevent unintended tissue sites from being exposed to harmful conditions.

Page 18

b. In regards to claim 22, Milder discloses a method comprising "transporting working fluid form a source through an inner channel of a probe to change a temperature of tissue adjacent the probe; transporting the working fluid through a concentric outer channel of the probe back to the source; sensing a first temperature of the tissue at a first location using a first temperature sensor coupled to the probe".

Milder does not disclose "sensing a second temperature of the tissue using a second temperature sensor spaced apart from the first temperature sensor; comparing the first and second temperature; and calculating a thermal transport property of the tissue based on the comparison". Attention is directed to the Lalonde et al. reference, which in a similar field of endeavor discloses sensing temperature of tissue at multiple locations, making a thermal transport property comparison from the sensed temperatures. It would have been obvious

Art Unit: 3739

to one having ordinary skill in the art using the teaching of Lalonde et al. to sense the temperature of tissue at a second location, to compare the sensed temperatures, and to evaluate the thermal transport properties of the tissue because it is beneficial to monitor the temperature of a tissue at a second location in order to prevent unintended tissue sites from being exposed to harmful conditions and to regulate the extent to which tissue is ablated.

Page 19

c. In regards to claim 23, Milder discloses a method comprising "transporting working fluid form a source through an inner channel of a probe to change a temperature of tissue adjacent the probe; transporting the working fluid through a concentric outer channel of the probe back to the source; sensing a first temperature of the tissue at a first location using a first temperature sensor coupled to the probe".

Milder does not disclose "sensing a second temperature of the tissue using a second temperature sensor spaced apart from the first temperature sensor; comparing the first and second temperature; and calculating a thermal transport property of the tissue based on the comparison to determine the health of the tissue". Attention is directed to the Lalonde et al. reference, which in a similar field of endeavor discloses sensing temperature of tissue at multiple locations, making a thermal transport property comparison from the sensed temperatures, and determining the health of the tissue based on the thermal transport property. It would have been obvious to one having ordinary skill in the art using the teaching of Lalonde et al. to sense the temperature of tissue at a

second location, to compare the sensed temperatures, and to determine the health of the tissue from thermal transport properties because it is beneficial to monitor the temperature of a tissue at a second location in order to prevent unintended tissue sites from being exposed to harmful conditions and to examine the health of the tissue.

d. In regards to claim 24, Milder discloses a method comprising "transporting working fluid form a source through an inner channel of a probe to change a temperature of tissue adjacent the probe; transporting the working fluid through a concentric outer channel of the probe back to the source; sensing a first temperature of the tissue at a first location using a first temperature sensor coupled to the probe".

Milder does not disclose "sensing a second temperature of the tissue using a second temperature sensor spaced apart from the first temperature sensor; comparing the first and second temperature; calculating a thermal transport property of the tissue based on the comparison to determine the health of the tissue; and determine whether the tissue is alive or dead". Attention is directed to the Lalonde et al. reference, which in a similar field of endeavor discloses sensing temperature of tissue at multiple locations, making a thermal transport property comparison from the sensed temperatures, and determining the health of the tissue based on the thermal transport property. It would have been obvious to one having ordinary skill in the art using the teaching of Lalonde et al. to sense the temperature of tissue at a second location, to compare the

Art Unit: 3739

sensed temperatures, and to determine the health of the tissue from thermal transport properties because it is beneficial to monitor the temperature of a tissue at a second location in order to prevent unintended tissue sites from being exposed to harmful conditions and to examine the health of the tissue.

e. In regards to claim 25, Milder discloses a method comprising "transporting working fluid form a source through an inner channel of a probe to change a temperature of tissue adjacent the probe; transporting the working fluid through a concentric outer channel of the probe back to the source; sensing a first temperature of the tissue at a first location using a first temperature sensor coupled to the probe".

Milder does not disclose "sensing a second temperature of the tissue using a second temperature sensor spaced apart from the first temperature sensor; comparing the first and second temperature; and adjusting the flow rate of the working fluid based on the comparison". Attention is directed to the Lalonde et al. reference, which in a similar field of endeavor discloses sensing temperature of tissue at multiple locations, making a comparison from the sensed temperatures and controlling the working fluid from the comparison data. It would have been obvious to one having ordinary skill in the art using the teaching of Lalonde et al. to sense the temperature of tissue at a second location, to compare the sensed temperatures because it is beneficial to monitor the temperature of a tissue at a second location in order to prevent unintended tissue sites from being exposed to harmful conditions.

Art Unit: 3739

f. In regards to claim 26, Milder discloses a method comprising "inserting a probe into the tissue, the probe having concentric passageways and a temperature sensor; and directing working fluid through the probe."

Page 22

Milder does not disclose "inserting a second temperature sensor into the tissue at a predetermined distance from the probe; and comparing the temperature sensed by the first temperature sensor to the temperature sensed by the second temperature sensor". Attention is directed to the Lalonde et al. reference, which in a similar field of endeavor discloses sensing temperature of tissue at multiple locations and making a comparison from the sensed temperatures. It would have been obvious to one having ordinary skill in the art using the teaching of Lalonde et al. to sense the temperature of tissue at a second location and to compare the sensed temperatures because it is beneficial to monitor the temperature of a tissue at a second location in order to prevent unintended tissue sites from being exposed to harmful conditions.

g. In regards to claim 27, Milder discloses a method comprising "inserting a probe into the tissue, the probe having concentric passageways and a temperature sensor; and directing working fluid through the probe."

Milder does not disclose "inserting a second temperature sensor into the tissue at a predetermined distance from the probe; comparing the temperature sensed by the first temperature sensor to the temperature sensed by the second temperature sensor; and determining the health of the tissue based on the comparison". Attention is directed to the Lalonde et al. reference, which in a

Page 23

similar field of endeavor discloses sensing temperature of tissue at multiple locations, making a comparison from the sensed temperatures and determining the health of the tissue based on the temperature comparison. It would have been obvious to one having ordinary skill in the art using the teaching of Lalonde et al. to sense the temperature of tissue at a second location, to compare the sensed temperatures, and determine the health of the tissue based on the temperature comparison because it is beneficial to monitor the temperature of a tissue at a second location in order to prevent unintended tissue sites from being exposed to harmful conditions.

h. In regards to claim 28, Milder discloses a method comprising "inserting a probe into the tissue, the probe having concentric passageways and a temperature sensor; and directing working fluid through the probe."

Milder does not disclose "inserting a second temperature sensor into the tissue at a predetermined distance from the probe; comparing the temperature sensed by the first temperature sensor to the temperature sensed by the second temperature sensor; and determining whether the tissue is alive or dead".

Attention is directed to the Lalonde et al. reference, which in a similar field of endeavor discloses sensing temperature of tissue at multiple locations, making a comparison from the sensed temperatures and determining the whether the tissue is alive or dead. It would have been obvious to one having ordinary skill in the art using the teaching of Lalonde et al. to sense the temperature of tissue at a second location, to compare the sensed temperatures, and determine the health

Art Unit: 3739

of the tissue based on the temperature comparison because it is beneficial to monitor the temperature of a tissue at a second location in order to prevent unintended tissue sites from being exposed to harmful conditions and to recognize the effect to the target tissue.

- 19. Claims 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lalonde et al. (U.S. Patent No. 6270493), further in view of Bliweis (U.S. Patent No. 6179831).
  - a. In regards to claim 29, Lalonde et al. discloses using a processor for "obtaining a first temperature sensed by a first temperature sensor coupled to a heat transfer probe; obtaining a second temperature of the tissue sensed by a second temperature sensor spaced apart from the first temperature sensor; comparing the first and second temperatures; and calculating a thermal transport property of the tissue".

Lalonde et al. does not disclose a computer readable media. Attention is directed to the Bliweis reference, which in a similar field of endeavor discloses a central processing unit (CPU) used to record and monitor temperature readings. It would have been obvious to one of ordinary skill in the art to use the teaching of Lalonde et al. to utilize a type of computer readable media to monitor temperature readings because the computer readable media are able to accomplish temperature monitoring in an efficient and precise manner.

b. In regards to claim 30, Lalonde et al. discloses using a processor for "obtaining a first temperature sensed by a first temperature sensor coupled to a

Art Unit: 3739

heat transfer probe; obtaining a second temperature of the tissue sensed by a second temperature sensor spaced apart from the first temperature sensor; comparing the first and second temperatures; calculating a thermal transport property of the tissue; and indicating the health of the tissue based on the thermal transport property".

Page 25

Lalonde et al. does not disclose a computer readable media. Attention is directed to the Bliweis reference, which in a similar field of endeavor discloses a central processing unit (CPU) used to record and monitor temperature readings. It would have been obvious to one of ordinary skill in the art to use the teaching of Lalonde et al. to utilize a type of computer readable media to monitor temperature readings because the computer readable media are able to accomplish temperature monitoring in an efficient and precise manner.

c. In regards to claim 31, Lalonde et al. discloses using a processor for "obtaining a first temperature sensed by a first temperature sensor coupled to a heat transfer probe; obtaining a second temperature of the tissue sensed by a second temperature sensor spaced apart from the first temperature sensor; comparing the first and second temperatures; calculating a thermal transport property of the tissue; indicating the health of the tissue based on the thermal transport property and indicating whether the tissue is alive or dead".

Lalonde et al. does not disclose a computer readable media. Attention is directed to the Bliweis reference, which in a similar field of endeavor discloses a central processing unit (CPU) used to record and monitor temperature readings.

Art Unit: 3739

It would have been obvious to one of ordinary skill in the art to use the teaching of Lalonde et al. to utilize a type of computer readable media to monitor temperature readings because the computer readable media are able to accomplish temperature monitoring in an efficient and precise manner.

Page 26

d. In regards to claim 32, Lalonde et al. discloses using a processor for "obtaining a first temperature sensed by a first temperature sensor coupled to a heat transfer probe; obtaining a second temperature of the tissue sensed by a second temperature sensor spaced apart from the first temperature sensor; comparing the first and second temperatures; calculating a thermal transport property of the tissue and providing a signal to a controller used for varying a flow rate of working fluid".

Lalonde et al. does not disclose a computer readable media. Attention is directed to the Bliweis reference, which in a similar field of endeavor discloses a central processing unit (CPU) used to record and monitor temperature readings. It would have been obvious to one of ordinary skill in the art to use the teaching of Lalonde et al. to utilize a type of computer readable media to monitor temperature readings because the computer readable media are able to accomplish temperature monitoring in an efficient and precise manner.

### Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth C. Williams whose telephone number is (571)272-8161. The examiner can normally be reached on Monday-Friday.

Art Unit: 3739

Page 27

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571)272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**KCW**